December 28, 2020

Fresenius Medical Care Renal Therapies Group, LLC
Denise Oppermann
Senior Director, Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Re: K203062
Trade/Device Name: Optiflux® Series of Dialyzers F160NR, F180NR, F200NR
Regulation Number: 21 CFR 876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: December 15, 2020
Received: December 16, 2020

Dear Denise Oppermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carolyn Y. Neuland, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203062

Device Name
Optiflux® Series of Dialyzers F160NR, F180NR, F200NR

Indications for Use *(Describe)*
Optiflux dialyzers are intended for hemodialysis, hemodiafiltration, hemofiltration, and isolated ultrafiltration in patients with acute kidney injury or chronic kidney disease when conservative therapy is judged to be inadequate.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

5.1. Submitter's Information

Name:	Fresenius Medical Care Renal Therapies Group, LLC
Address:	920 Winter Street Waltham, MA 02451-1457
Phone:	(781) 996-9103
Fax:	(781) 699-9635
Contact Person:	Denise Oppermann, Senior Director Regulatory Affairs – Devices
Preparation Date:	08 October 2020

5.2. Device Name

Trade Name:	Optiflux® Series of Dialyzers F160NR, F180NR, F200NR
Common Name:	Dialyzer
Regulation Name:	High permeability hemodialysis system
Regulatory Class:	Class II per 21 CFR § 876.5860
Product Code:	KDI
Product Code Name:	Dialyzer, High Permeability with or without sealed dialysate system
FDA Review Panel:	Gastroenterology-Urology

5.3. Legally Marketed Predicate Device

The legally marketed predicate devices are the F160NR, F180NR and F200NR Optiflux Dialyzers cleared under K162488. These predicates have not been subject to a design-related recall.

The Gambro Polyflux 140H, 170H, and 210H Capillary Dialyzers (K043342) will be used as secondary predicate devices to support the expanded Indications for Use statement.

5.4. Device Description

The Optiflux dialyzers are part of the FMCRTG family of single use dialyzers which allow for the transfer of water and solutes between blood and the dialysate through a semi-permeable membrane. The Optiflux dialyzers are available in three (3) sizes. The sizes are differentiated by housing size, fiber count per bundle, and effective membrane surface area.

5.4.1. Device Identification

The proposed Optiflux dialyzers include the following sizes/models:

- Optiflux® F160NR Dialyzer
- Optiflux® F180NR Dialyzer
- Optiflux® F200NR Dialyzer

5.4.2. Device Characteristics

The Optiflux dialyzers are single use dialyzers manufactured from Advanced Fresenius polysulfone, polycarbonate, silicone, polyurethane, and high-density polyethylene. The dialyzers are provided with the blood pathway sterile and non-pyrogenic. The dialyzers are sterilized using e-beam radiation.

5.4.3. Environment of Use

Optiflux dialyzers are used in environments where acute and chronic dialysis are performed.

5.4.4. Brief Written Description of the Device

Optiflux dialyzers are high-flux, sterile devices designed for single use hemodialysis and hemodiafiltration for the treatment of acute kidney injury or chronic kidney disease. The dialyzer is configured to connect to a bloodline set which connects to a patient's vascular access system when used with a dialysis machine equipped with ultrafiltration control. During treatment, blood is pumped from the patient's body through an extracorporeal circuit, one component of which is the dialyzer. The dialyzer contains a semi-permeable membrane that allows for diffusion and/or convection to transport toxins and excess fluid from the blood compartment (fiber lumen) to the dialysate or filtrate compartment. Dialyzers utilize a counter-current flow in which dialysate and blood flow in opposite directions in the dialyzer during hemodialysis. The counter-current flow maintains the concentration gradient across the membrane for waste and fluid removal.

5.4.5. Materials of Use

The Optiflux dialyzers are classified as externally communicating, circulating blood, prolonged contact (> 24 hours to 30 days) duration, Class II (Category B) devices in accordance with FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* (04 September 2020).

The materials used in the manufacture of the components of the Optiflux dialyzers are listed in Table 1.

Table 1: Optiflux Dialyzer Component Materials

Component	Material
Housing	Polycarbonate
Potting Resin	Polyurethane
Fiber Bundle	Advanced Fresenius Polysulfone
Screw Flange	Polycarbonate
O-ring	Silicone
Blood Port Cap(s)	High Density Polyethylene
Dialysate Port Cap	High Density Polyethylene

5.4.6. Key Performance Specifications and Characteristics

Urea clearance is a key performance specification of the Optiflux dialyzers. FMCRTG uses sodium clearance as a marker for urea clearance because sodium and urea exhibit similar movement across a membrane. Urea clearance data from the Instructions for Use (IFU) for the Optiflux series of dialyzers is provided in Table 2, where Q_b= blood flow rate, Q_d= dialysate flow rate, and Q_f = filtration flow rate. The Q_f is equal to the ultrafiltration flow rate (Q_{uf}) plus the substitution flow rate (Q_s), where Q_s=0 in hemodialysis.

Table 2: *In vitro* Urea Clearance for Optiflux Dialyzers*

Trade Name	Typical Urea Clearance (Sodium Used as Marker)	
	Q_f = 0 mL/min	**Q_f = 75 mL/min**
Optiflux F160NR Dialyzer	271	285
Optiflux F180NR Dialyzer	277	285
Optiflux F200NR Dialyzer	280	289

* Q_b = 300 mL/min, Q_d = 500 mL/min

5.5. Intended Use

Optiflux dialyzers are designed for single use hemodialysis and hemodiafiltration for the treatment of acute kidney injury or chronic kidney disease.

5.6. Indications for Use

Optiflux dialyzers are intended for hemodialysis, hemodiafiltration, hemofiltration, and isolated ultrafiltration in patients with acute kidney injury or chronic kidney disease when conservative therapy is judged to be inadequate.

5.7. Comparison of Technological Characteristics with the Predicate Device

The following technological characteristics of the proposed Optiflux dialyzers are equivalent to the predicate Optiflux dialyzers (K162488) and the secondary predicate Gambro Polyflux 140H, 170H, and 210H Capillary Dialyzers (K043342):

- Intended use
- Design and configuration
- Identical sterilization method, packaging, and sterility label claims as the predicate dialyzers
- Identical materials as the predicate dialyzers – Advanced Fresenius polysulfone, polycarbonate, polyurethane, silicone, and high-density polyethylene

5.8. Performance Data

Performance testing was conducted in accordance with ISO 8637-1:2017 and *Guidance for the Content of Premarket Notifications for Conventional and High Permeability Hemodialyzers, August 1998*. Testing conducted to support the expanded Indications for Use statement and increased maximum dialysate flow rate is summarized in Table 3.

Table 3: Performance Testing Summary

Test Conducted	Test Method Description
Clearance – Sodium (marker for urea), Creatinine, Phosphate, Vitamin B_{12}, β2-Microglobulin	Calculated by analyzing test samples over the specified range of blood, dialysate, and filtration flow rates.
Protein Sieving Coefficient	The test circuit was stabilized for blood and filtrate flows. All air was removed from the dialyzer. Paired samples for blood and filtrate flows were collected after 15 min. Samples were taken again after another 15 min. The sieving coefficient was calculated in accordance with Section 5.6.2.4 of ISO 8637-1:2017.
Pressure Drop	The dialysate and blood compartments were filled with dialysate and bovine blood, respectively. Inlet and outlet pressures of the blood and dialysate compartments were measured across the range of flow rates with the dialyzers in a horizontal position.

Table 3: Performance Testing Summary

Test Conducted	Test Method Description
Blood Kuf	Calculated as the slope from a plot of the measured transmembrane pressure versus the ultrafiltration rate.

Results of all testing met predetermined acceptance criteria and demonstrated that, like the predicate devices, the Optiflux dialyzers are safe and effective for their intended use.

5.8.1. Biocompatibility Testing

Testing was performed to confirm the biological safety of the Optiflux dialyzers in support of the labeling changes:

- Hemocompatibility, Mechanical Hemolysis

5.8.2. Human Factors Validation Testing

A Human Factors assessment was conducted for the Optiflux dialyzers to demonstrate their safe and effective use in accordance with FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices* (03 February 2016).

5.8.3. Electrical Safety and Electromagnetic Compatibility (EMC)

Not applicable. The Optiflux dialyzers are not electrical mechanical devices.

5.8.4. Software Verification and Validation Testing

Not applicable. The Optiflux dialyzers do not contain software.

5.8.5. Animal Studies

No animal studies were performed.

5.8.6. Clinical Studies

No clinical studies were performed.

5.9. Conclusion

The intended use, design and configuration, and materials of the Optiflux dialyzers are substantially equivalent to those of the predicate and secondary predicate devices. Testing and evaluations that were conducted to support the expanded Indications for Use statement and increased maximum dialysate flow rate, address the safety of the Optiflux dialyzers, and demonstrate that the Optiflux dialyzers perform as intended in the specified use conditions. FMCRTG concludes that within the meaning of the Medical Device Amendments Act of 1976, the Optiflux dialyzers are safe and effective for their intended use.